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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/517,653	03/08/2005	Adrian Keith West	47-217	5626

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EXAMINER	
KOLKER, DANIEL E	
ART UNIT	**PAPER NUMBER**
1649	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/517,653	WEST ET AL.	
	Examiner	Art Unit	
	Daniel Kolker	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 June 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1/4/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☒ Other: *Translation of FR 2813529*.

DETAILED ACTION

1. The remarks filed 11 June 2007 have been entered. No claim amendments have been filed. Claims 1 – 27 are pending.

Election/Restrictions

2. Applicant's election with traverse of Group I (claims 1 – 17 and 26) in the reply filed on 11 June 2007 is acknowledged. The traversal is on the ground(s) that the reference by Ebadi (1998, of record) fails to teach the method recited in claim 1 and therefore does not provide evidence of lack of a special technical feature. This is persuasive. A through review of Ebadi indicates that the reference does not explicitly teach contacting "a target neuron or neuronal area" to MT-IIA.

Therefore, the restriction requirement set forth in the office action mailed 11 April 2007 is vacated. Claims 1 – 27 are pending and under examination.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 26 and 27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite in that it fails to point out what is included or excluded by the claim language. These claims are omnibus type claims. See MPEP § 2173.05(r).

Priority

4. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Information Disclosure Statement

5. The IDS filed 4 January 2005 has been considered. The IDS filed 13 December 2004 is duplicative and therefore has not been separately considered. Every reference cited on the 13 December 2004 has been indicated as considered; note the examiner's initials on the IDS filed 4 January 2005.

Claim Rejections - 35 USC §§ 102 and 103

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1 – 2, 4, 13, 18, 21, and 23 – 27 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over by Penkowa (2002. Journal of Comparative Neurology 444(2):174-189), as evidenced by Sigma M9542 and Garrett (2000. The Prostate 43:125 – 135).

The Table of Contents for volume 444, issue 2, of this journal indicates that the article by Penkowa was published online on 29 January 2002; see Table of Contents, attached to the article. As the reference was filed more than a year before the filing date of PCT/AU03/00735, it qualifies as prior art under 35 USC § 102(b).

Penkowa teaches administering metallothionein 2 (also called MT-2 in the reference) to mice. At p. 176 first paragraph the reference teaches administering the compound to normal mice, some of which had been treated with the compound 6-AN which damages the brain (see p. 175 second column). Note that the MT-2 was administered as Zn-MT-2 however some

animals were administered ZnCl as a control, so that any effects observed could reasonably be attributed to the MT-2 itself as opposed to the zinc. The Zn-MT-2 was administered by the intraperitoneal route (p. 184, end of first column), which is a route that allows for neural repair to occur (specification, p. 2 lines 30 – 35). Penkowa teaches that treatment with MT-2 reduced 6-AN-induced degeneration of the gray matter (p. 177, last paragraph of the first column) and decreased the number of recruited lymphocytes in damaged brain tissue (p. 180, first complete paragraph). Penkowa teaches that the administration of MT-2 decreased the number of apoptotic (i.e., dying) cells (p. 183, second column). While the reference did not explicitly measure "stimulating neuronal growth or repair" as recited in claim 1, it is reasonable that these in fact did occur, as Penkowa performed all the active steps recited in the method (i.e., by administering the MT-2 to a subject). Furthermore, it is noted that those phenomena measured by Penkowa are consistent with increased health of brain tissue, much as stimulating repair is associated with increased health of the tissue.

The reference by Penkowa explicitly teaches every limitation of claim 1, with the exception of "MT-IIA" as recited. The reference teaches that Zn-MT-2 was purchased from Sigma as catalog number M9542. The enclosed printout from Sigma indicates that this is rabbit MT-2. Neither the Penkowa nor the Sigma references disclose whether this MT-2 is MT-2A. However, the reference by Garrett teaches that in humans, MT-2A is the only active MT-2 isoform (p. 126 first complete paragraph). Thus it appears that the MT-2 administered by Penkowa is in fact MT-2A, as recited in claim 1. Therefore, claim 1 is anticipated by, or in the alternative obvious over, Penkowa. See MPEP §§ 2131.02 and 2144.08.

Claim 2 is rejected as Penkowa states that Zn-MT-2 reaches the brain; see p. 186, first column. Claim 4 is rejected as it recites a product-by-process limitation ("wherein said MT-IIA is produced by chemical synthesis or by production in genetically manipulated cells or organisms"). Although this is not a product-by-process claim *per se*, as the claim is drawn to a method, the product-by-process limitation refers to the starting material. There is no evidence of record that the product made by the processes recited in claim 4 are any different than those made by other means. As the Penkowa reference anticipates (or renders obvious) claim 1, the same teachings apply to claim 4, which is drawn to administering the same product, even though it might be made by a different process. Claim 13 is rejected as Penkowa teaches intraperitoneal injection (see p. 184, end of first column).

Claim 18 is rejected as Penkowa teaches the therapeutic composition comprising MT-2 as an active ingredient. The claim recites "adapted for topical administration" but does not list any particular components which must be present in the composition beyond the active ingredient. The "adapted for" language can reasonably be interpreted as an intended use and need not be given patentable weight, particularly in light of the fact that the claim lists only a single component. The Zn-MT-2 administered by Penkowa was in saline (note p. 176 first paragraph which teaches saline as a control), which is appropriate for topical administration. Claim 21 is rejected as it recites a product-by-process limitation. The claimed product, a composition comprising MT-IIA, is the same as the prior art composition comprising MT-2. Claim 23 is rejected as the sodium chloride solution (i.e. saline) in which the Zn-MT-2 is dissolved can be considered "a neurologically acceptable carrier" as it allows the product to enter the brain and because it is "particularly adapted for a topical administration", since the saline is physiologically and topically acceptable. Note that no specific components are listed in claim 23 other than the "carrier". Claim 24 is rejected as the composition in Penkowa could be used for direct topical application. It is reasonable that the saline will be physiologically acceptable to skin. Claim 25 is rejected as the reference clearly demonstrates the composition is suitable for i.p. administration (p. 184, end of first column).

Claims 26 and 27 are omnibus claims. The claims add no additional steps (for the method, claim 26) or structural features (for the product, claim 27) beyond those recited in the base claims. As the claims 26 and 27 each depend from a rejected base claim but add no further limitations, they are rejected for the same reasons the base claims are rejected.

8. Claims 1 – 2, 4, 13, 17 – 18, 21, and 23 – 27 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Giralt (2002. Experimental Neurology 173:114-128, available online 25 February 2002).

Giralt teaches administering Zn-MT-2 to mice that had received a head injury. The injury is described at p. 115 third paragraph. Note that while much of the reference discusses the effects of transgenes on injury recovery, Giralt clearly teaches that control mice were subjected to the same injury paradigm and then treated with MT-2; see p. 115 first column last complete paragraph; see also p. 120. The reference teaches that the MT-2 was administered as Zn-MT-2 however some animals were administered ZnCl as a control, so that any effects observed could reasonably be attributed to the MT-2 itself as opposed to the zinc. The Zn-MT-2 was

administered by the intraperitoneal route (p. 115, "Injection of Zn-MT-2"), which is a route that allows for neural repair to occur (specification, p. 2 lines 30 – 35). Giralt teaches that MT-2 administration to mice with head injury decreased oxidative stress and apoptosis (cell death); see p. 120 second column. While the reference did not explicitly measure "stimulating neuronal growth or repair" as recited in claim 1, it is reasonable that these in fact did occur, as Giralt performed all the active steps recited in the method (i.e., by administering the MT-2 to a subject). Furthermore, it is noted that those phenomena (such as decreased apoptosis) measured by Giralt are consistent with increased health of brain tissue, much as stimulating repair is associated with increased health of the tissue. Giralt therefore explicitly teaches every element of claim 1, with the exception of whether the MT-2 used was MT-2A. It is noted that Giralt used Sigma M9542 (p. 115 first column). As set forth in the rejection over Penkowa above, this product appears to be indistinguishable from MT-IIA recited in claim 1, as MT-IIA is the only active form of MT-2. Therefore, claim 1 is anticipated by, or in the alternative obvious over, Giralt. See MPEP §§ 2131.02 and 2144.08.

Claim 2 is rejected as Giralt teaches that Zn-MT-2 reaches the brain; see p. 120, first column final paragraph. Claim 4 is rejected as it recites a product-by-process limitation ("wherein said MT-IIA is produced by chemical synthesis or by production in genetically manipulated cells or organisms"). Although this is not a product-by-process claim *per se*, as the claim is drawn to a method, the product-by-process limitation refers to the starting material. There is no evidence of record that the product made by the processes recited in claim 4 are any different than those made by other means. As the Giralt reference anticipates (or renders obvious) claim 1, the same teachings apply to claim 4, which is drawn to administering the same product, even though it might be made by a different process. Claim 13 is rejected as Giralt teaches intraperitoneal injection (see p. 115, end of first column).

Claim 17 is rejected as Giralt explicitly teaches treating head injury by administering MT-2 (see p. 115 and 120). Claim 18 is rejected as Giralt teaches the therapeutic composition comprising MT-2 as an active ingredient. The claim recites "adapted for topical administration" but does not list any particular components which must be present in the composition beyond the active ingredient. The "adapted for" language can reasonably be interpreted as an intended use and need not be given patentable weight, particularly in light of the fact that the claim lists only a single component. The Zn-MT-2 administered by Giralt was in saline (note p. 115 first column final paragraph which teaches saline as a control), which is appropriate for topical

administration. Claim 21 is rejected as it recites a product-by-process limitation. The claimed product, a composition comprising MT-IIA, is the same as the prior art composition comprising MT-2, even though it might be made by a different method. Claim 23 is rejected as the sodium chloride solution (i.e. saline) in which the Zn-MT-2 is dissolved can be considered "a neurologically acceptable carrier" as it allows the product to enter the brain and because it is "particularly adapted for a topical administration", since the saline is physiologically and topically acceptable. Note that no specific components are listed in claim 23 other than the "carrier". Claim 24 is rejected as the composition in Giralt could be used for direct topical application. It is reasonable that the saline will be physiologically acceptable to skin. Claim 25 is rejected as the reference clearly demonstrates the composition is suitable for i.p. administration (p. 115, end of first column).

Claims 26 and 27 are omnibus claims. The claims add no additional steps (for the method, claim 26) or structural features (for the product, claim 27) beyond those recited in the base claims. As the claims 26 and 27 each depend from a rejected base claim but add no further limitations, they are rejected for the same reasons the base claims are rejected.

9. Claims 18, 20 – 25, and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by FR 2813529 (hereinafter '529 publication), cited on IDS filed 13 December 2004. Note the enclosed translation, which refers to page numbers in the original document in the right-hand margin. The page and line numbers referred to herein are those of the original French document.

'529 publication teaches that there are several types of metallothionein, including human MT-2 (see p. 6 lines 17 – 26 and Table 1 which provides the specific disclosure of human MT-2). The reference teaches that MT-2 is also known as MT-2A, and should be used in the pharmaceutical compositions described in the invention (see p. 18, lines 10 – 17). Thus the human MT-2 disclosed in '529 publication's Table 1 is in fact MT-2A, as recited in claim 18. '529 specifically teaches compositions comprising MT-2, including those adapted for topical administration such as gels, creams, pomades, and body lotions; see p. 10 line 2 – 16. Note that '529 specifically teaches "that the invention's compounds be formulated in order to be applied to exposed parts of the body", which indicates the compositions are "adapted for topical administration" as recited in claim 18. See also p. 10 lines 27 – 30.

'529 publication also teaches that the MT-2 (or MT-2A) to be used is the human MT-2A; see p. 18 lines 10 – 17 and Example 3, which teaches the MT-IIA incorporated into several topical compositions, thereby anticipating claim 20. Claims 21 – 22 are rejected as '529 specifically teaches methods of making recombinant human MT-IIA for use in the topical compositions (see examples 1 – 3). Claim 23 is rejected as '529 teaches a composition which also includes the neurologically acceptable carrier water (see Example 3, bath gel, which includes water). Claim 24 is rejected as it depends from claim 23 but recites no additional components. Note that many of the compositions listed in Example 3 are suitable "for direct topical application" as recited in claim 24, including bath gel, liquid soap, and shampoos. Claim 25 is anticipated as '529 explicitly teaches MT-IIA in a test tube with tris-HCl buffer at pH 7.0 (p. 16 lines 26 – 31). Tris –HCl buffer is suitable for intravenous or intraperitoneal administration as recited in claim 25, so the disclosure of the composition comprising MT-IIA and Tris buffer anticipates claim 25. Claim 27 is an omnibus claim. The claim adds no additional structural features beyond those recited in base claim 18. As claim 27 depends from rejected base claim 18 but adds no further limitations, it is rejected for the same reasons the base claim is rejected.

10. Claims 18 – 25 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over FR 2813529.

The reasons why claims 18, 20 – 25, and 27 are anticipated by FR 2813529 are set forth in the rejection under 35 USC 102 above. While the reference teaches that any one of several isoforms of MT can be used in the compositions, including MT-IA which is a type of MT-I as recited in claim 19 (see '529 publication, p. 7 lines 7 – 22), '529 publication does not explicitly teach compositions comprising MT-IIA and an isoform selected from MT-1, MT-II, MT-III, or MT-IV, as recited in claim 19.

It would have been obvious to one of ordinary skill in the art to include MT-IA along with MT-IIA, as suggested by '529 publication, with a reasonable expectation of success. It is prima facie obvious to combine equivalents known for the same purpose; see MPEP § 2144.06. Here, '529 publication discloses that both MT-IIA and MT-IA are effective for protecting skin against ultraviolet rays, and teaches a composition comprising the former. As the latter is known to be effective for the same purpose, it would have been obvious to add it to the composition, thereby arriving at the invention of claim 19.

11. Claims 1 – 2, 4, 6 – 13, 18, 21, and 23 – 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Penkowa (2002. Journal of Comparative Neurology 444(2):174-189).

The reasons why claims 1 – 2, 4, 13, 18, 21, and 23 – 27 are anticipated by or obvious over Penkowa are set forth above. While the reference teaches administering a total of 17.5 ug Zn-MT-2 in saline per day, divided into three separate doses (p. 176 first paragraph), Penkowa does not explicitly teach that the solution has a concentration of "up to about 5 ug/ml" as recited in claim 6 or "about 5 ug/ml" as recited in claim 7. Additionally, Penkowa teaches that endogenous MT-1, transcribed off a transgene, is sufficient to reduce CNS degeneration. See p. 180 second column, second complete paragraph, which indicates that MT-1 protein is overexpressed in TgMTI* mice and p. 183, paragraph spanning the two columns, which indicates that transgenic mice are less susceptible to cell death following 6-AN administration. While Penkowa teaches the efficacy of MT-I in decreasing neural cell death, the reference does not explicitly teach administering this protein as encompassed by claims 8 – 11, as the protein is endogenous to the transgenic mice.

It would have been obvious to one of ordinary skill in the art to adjust the concentration of MT-2 administered by Penkowa. Changing the concentration of a composition is not supportive of patentability (MPEP § 2144.05(II)(A)). As Penkowa teaches a method according to claims 6 – 7 that differs only in that the prior art does not disclose the actual concentration of the composition, and altering the concentration of the active ingredient would have been obvious to one of ordinary skill in the art, claims 6 – 7 are unpatentable over Penkowa. The motivation to alter the concentration of the active ingredient would be to find a volume of injection suitable for the patient.

It also would have been obvious to one of ordinary skill in the art to coadminister MT-1 along with MT-2, with a reasonable expectation of success. The motivation to do so would be to provide additional neuronal protection. Both MT-2 and MT-1 are shown by Penkowa to be useful for protecting neurons. It is prima facie obvious to combine equivalents known for the same purpose; see MPEP § 2144.06. Therefore, the inventions of claims 8 and 9 would have been obvious to one of ordinary skill in the art. Claims 10 – 11 also would have been obvious, as they only require that the exposure to MT-1 and MT-IIA be sequential. Altering the order of administration would have been obvious to one of ordinary skill in the art, much as rearranging parts on an apparatus is generally considered obvious (see MPEP § 2144.04(VI)(C)). Claim 12

is rejected as it depends from claim 11 and only requires that the neuron is in the brain; Penkowa clearly teaches that the metallothioneins are able to protect neurons in the brain.

12. Claims 1 – 13 and 18 – 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Penkowa (2002. Journal of Comparative Neurology 444(2):174-189) in view of FR 2813529, cited on IDS filed 13 December 2004.

The reasons why claims 1 – 2, 4, 6 – 13, 18, 21, and 23 – 27 are anticipated by or obvious over Penkowa are set forth above. Briefly Penkowa teaches administration of MT-IIA is protective of neurons, and teaches compositions comprising MT-IIA. Penkowa suggests that metalliothioneins can be used in treating CNS diseases (p. 187 end of first column). However Penkowa used rabbit metallothionein, and does not teach administration of human MT-IIA as recited in claims 3 and 5.

The reasons why claims 18 – 25 and 27 are anticipated by, or obvious over, '529 publication are set forth above. Breifly, '529 teaches compositions comprising human MT-IIA, which are within the scope of claims 18 – 25 and 27, and are on point to claims 3 and 5. However '529 publication does not teach administering the compositions such that target neurons or neuronal areas are exposed to the MT-IIA-containing compositions.

It would have been obvious to one of ordinary skill in the art to modify the methods of Penkowa to use the human MT-IIA taught in '529 publication, with a reasonable expectation of success. The motivation to do so would be to ensure less of an immune response when treating human patients. The artisan would be motivated to make this substitution, thereby arriving at the invention of claims 3 and 5, because the human MT-IIA sequence was known in the art and shown by '529 publication to be suitable for administration to humans, and because the artisan of ordinary skill would immediately understand that using a protein from a foreign species would increase the likelihood of an adverse immune reaction.

13. Claims 1 – 2, 4, 6 – 13, 15, 18, 21, and 23 – 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Penkowa (2002. Journal of Comparative Neurology 444(2):174-189) in view of Asanuma (2002. Neuroscience Letters 327:61-65; available online 21 April 2002).

The reasons why claims 1 – 2, 4, 6 – 13, 18, 21, and 23 – 27 are anticipated by or obvious over Penkowa are set forth above. Briefly Penkowa teaches administration of MT-IIA is protective of neurons, and teaches compositions comprising MT-IIA. Penkowa suggests that

metalliothioneins can be used in treating CNS diseases (p. 187 end of first column). However Penkowa does not explicitly teach a method of treating Parkinson's disease by administering metallothioneins as encompassed by claim 15.

Asanuma teaches that mice which lack both MT-I and MT-II are exceptionally susceptible to the toxic effects of 6-OH dopamine. See for example Figure 1, top panels. 6-OHDA is a chemical used to kill dopaminergic neurons, and administration of 6-OHDA is an art accepted animal model of Parkinson's disease. Asanuma teaches that the results indicate that both MT-I and MT-II have neuroprotective effects for Parkinson's (see p. 63 final paragraph), and suggest that the protective effects of these proteins are consistent with their known free-radical-scavenging roles. However Asanuma does not explicitly teach administering MT-IIA for treatment of Parkinson's disease as recited in claim 15.

It would have been obvious to one of ordinary skill in the art to administer MT-IIA, as taught by Penkowa, for treatment of Parkinson's disease, as suggested by Asanuma. The motivation to do so would be to effectively treat the disease. It would be reasonable for the artisan of ordinary skill to expect success, as Asanuma teaches that the lack of MT-I and MT-II leads to increased likelihood of death of dopaminergic neurons, the cause of Parkinson's disease, in the presence of certain toxins. Additionally Asanuma teaches the free-radical scavenging properties of these proteins, and teaches how these properties would be helpful in treatment of Parkinson's.

14. Claims 1 – 2, 4, 6 – 14, 16, 18, 21, and 23 – 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Penkowa (2002. Journal of Comparative Neurology 444(2):174-189) in view of Walsh (US Patent Application Publication 2002/0155170, published 24 October 2002, filed 30 November 2001, claiming benefit of a provisional application filed 30 November 2000).

The reasons why claims 1 – 2, 4, 6 – 13, 18, 21, and 23 – 27 are anticipated by or obvious over Penkowa are set forth above. Briefly Penkowa teaches administration of MT-IIA is protective of neurons, and teaches compositions comprising MT-IIA. Penkowa suggests that metalliothioneins can be used in treating CNS diseases (p. 187 end of first column). However Penkowa does not explicitly teach a method of treating Alzheimer's disease by administering metallothioneins as encompassed by claim 14 or treatment of motor neuron disease as recited in claim 16.

Walsh teaches that Alzheimer's disease (AD) is likely caused by a metallothionein disorder; see paragraphs [0118] – [0119]. Specifically, Walsh teaches that the plaques associated with AD results from free Cu and Zn ions, and that these plaques as well as the symptoms of AD will be ameliorated by metallothioneins. Walsh also teaches that familial amyotrophic lateral sclerosis symptoms worsen when metallothionein levels decrease (paragraph [0120]); this is a specific type of motor neuron disease. Walsh teaches and claims administration of a pharmaceutical composition which increases the amount of metallothioneins for treatment of Alzheimer's disease and the motor neuron disease familial amyotrophic lateral sclerosis, which is on point to instant claims 14 and 16 (see Walsh paragraph [0120] and claims 42 – 43). However Walsh does not teach administering MT-IIA for treatment of Alzheimer's disease as recited in claim 14 or for treatment of motor neuron disease.

It would have been obvious to one of ordinary skill in the art to administer MT-IIA, as taught by Penkowa, for treatment of Alzheimer's disease and the motor neuron disease, as suggested by Walsh. The motivation to do so would be to effectively treat the diseases. It would be reasonable for the artisan of ordinary skill to expect success, as Walsh teaches that both AD and familial ALS are correlated with decreased metallothionein levels, and teaches that the way to treat these diseases is to administer compositions which raise MT levels. It would be reasonable to expect success, as Walsh teaches that the compositions are suitable to increase MT-II levels (see paragraph [0032] for example), and Penkowa teaches that exogenously administered metallothioneins, particularly MT-IIA, are useful as neuroprotectants.

Conclusion

15. No claim is allowed.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel Kolker whose telephone number is (571) 272-3181. The examiner can normally be reached on Mon - Fri 8:30AM - 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Patent Examiner
Daniel E. Kolker, Ph.D.
September 5, 2007